



Billing Code: 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Delisting for Cause for Independent Data Safety Monitoring, Inc.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Delisting.

SUMMARY: AHRQ has delisted Independent Data Safety Monitoring, Inc. due to its failure to correct a deficiency. The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on January 15, 2013.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.AHRQ.gov/index.html>

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: psaHRQ.hhs.gov

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, Pub. L. 109-41, 42 U.S.C. 299b-21 b-26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule, 42 CFR part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ``delisted'' by the Secretary if it is found no longer to meet the requirements of the Patient Safety Act and Patient Safety Rule. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

Independent Data Safety Monitoring, Inc. failed to respond to a Notice of Preliminary Finding of Deficiency sent by AHRQ pursuant to 42 CFR 3.108(a)(2) and a Notice of Proposed Revocation and Delisting sent by AHRQ pursuant to 42 CFR 3.108(a)(3)(iii)(C) which found that Independent Data Safety Monitoring, Inc. had not complied with its attestation to notify the Secretary if there has

been a change in the accuracy of the information it submitted for initial listing, which includes contact information for the PSO (42 CFR 3.102(a)(1)(vi)). Independent Data Safety Monitoring, Inc. did not exercise its opportunity to be heard in writing to respond to the deficiency specified in the notices, and has not provided any evidence of a good faith effort to correct the deficiency. As such, pursuant to 42 CFR 3.108(a)(4)(iii), the notice of proposed revocation became final as a matter of law and the basis for revocation.

Accordingly, AHRQ has revoked the listing of Independent Data Safety Monitoring, Inc., PSO number P0114, effective at 12:00 Midnight ET (2400) on January 15, 2013.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>

Dated: February 11, 2013.

Carolyn M. Clancy, M.D.

Director